REMARKS

Claims 31, 34-42, and 60-64 were pending in this application. Applicants have amended claims 31, 37, and 40, and have canceled 38, 39, and 64. Accordingly, after entry of this paper, claims 31, 34-37, 40-42, and 61-63 will be pending in this application. Applicants submit that these amendments add no new matter.

Interview Summary

Applicants would like to thank Examiner Yabut for her time and helpful suggestions during the telephonic interview of May 8, 2008. Therein, Applicants representatives discussed with the Examiner the rejection of claim 31 in view of Ginn and Roe and claim 37 in view of Roe and Das. Applicants discussed with the Examiner the amendments to claims 31 and 37 presented herein. No agreement was reached.

Amendments to the Claims

Independent claim 31 is amended to recite that the second free end portion of the first flexible member is introduced through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale, and exiting the opening of the patent foramen ovale on the left atrial side. Support for this amendment is found in the application as originally filed, for example, at lines 4-7 of paragraph 4; lines 1-3 of paragraph 70; lines 7-10 of paragraph 71; and in FIGS. 9 and 10A-C.

Independent claim 37 is amended to recite introducing at least one of said hexagonally shaped flexible members through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through a septum primum. A hole is introduced through the septum primum from the right atrial side of the septum primum to the left atrial side of the septum primum. An occlusion device is introduced for occluding the patent foramen ovale through the hole in the septum primum. Support for this amendment is found in the application as originally filed, for example, at lines 4-7 of paragraph 4; at lines 1-3 of paragraph 70; lines 14-17 of paragraph 74; at

lines 15-19 of paragraph 79; at paragraphs 81 and 82; in FIG. 12A-C; in FIG. 13; and in claims 38 and 39 as originally filed.

Claim 40 is amended to correct the dependency.

Applicants submit that these amendments add no new matter.

Claim Rejections under 35 U.S.C. § 103

Claims 31, 34, 35, and 60-63 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent No. 6,702,835 to Ginn ("Ginn") in view of U.S. Patent No. 6,780,197 to Roe ("Roe"). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claim 31 has been amended to recite introducing the second free end portion of the first flexible member through the opening of the patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through the septum primum.

Ginn teaches an apparatus and methods for closing a septal defect. According to Ginn, a needle is advanced through a patient's vasculature into the heart until the needle is disposed adjacent the septum. The needle is then directed through the septum, creating a puncture, and passing through the septum until the needle is disposed in the opposite chamber on the other side of the septum. (See abstract; col. 7, line 60 to col. 8, line 38; and FIGS. 5A-C).

Roe teaches a device for delivering a closure element, such as a staple, for closing vascular puncture sites, for example, in blood vessels (col. 1, lines 16-18; col. 3, lines 26-31). Roe does not teach using his device in the heart, let alone, to close a patent foramen ovale.

Nevertheless, the Office action alleges that the combined teachings of Ginn and Roe render Applicants' invention obvious. Applicants respectfully disagree.

As previously stated, Applicants invention requires introducing the second free end portion of a first flexible member through the opening of the patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side. Applicants submit that neither Ginn nor Roe teaches this step.

In particular, Ginn teaches only that Ginn's puncture device travels from one atrial side of the heart to the other by puncturing through the septum. Ginn does not teach introducing Ginn's puncture device through the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale, and exiting the opening of the patent foramen ovale on the left atrial side. Moreover, Ginn does not teach or suggest the claimed order of steps requiring introducing the flexible member through the tunnel of the patent foramen ovale prior to introducing a hole through the septum primum.

Further, Roe's device enters a puncture in a vessel wall to deliver a closure element such as a staple. Roe does not teach that any portion of Roe's device passes through a naturally occurring tunnel such as a patent foramen ovale. Nor does Roe teach introducing a flexible member through the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side.

Accordingly, Applicants respectfully submit that claim 31 is not obvious over Ginn in view of Roe. Because claims 34, 35, and 60-63 depend from claim 31, Applicants submit that these claims are patentable at least for the same reasons that claim 31 is patentable. Therefore, Applicants respectfully request that the rejection of claims 31, 34, 35, and 60-63 over Ginn in view of Roe be reconsidered and withdrawn.

Claim 36 stands rejected as being obvious over Ginn in view of Roe and U.S. Patent No. 5,749,895 to Sawyer ("Sawyer"). Claim 36 depends from claim 31. Applicants submit that claim 36 is patentable at least for the same reasons that claim 31.

Further, Applicants submit that Sawyer fails to remedy the deficiencies of Ginn and Roe as applied to claim 31. In particular, Sawyer does not teach introducing a flexible member through the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side. In fact, Sawyer does not even teach patent foramen ovales. Rather, Sawyer is directed to methods for joining tissue by using a patch and a mechanical support (abstract; col. 2, lines 39-55).

Accordingly, Applicants respectfully request that the rejection of claim 36 over Ginn in view of Roe and Sawyer be reconsidered and withdrawn.

Claims 37 and 40 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Roe in view of U.S. Patent No. 5,334,217 to Das ("Das"). Applicants traverse the rejection to the extent it is maintained over the claim as amended.

Claim 37 has been amended to recite introducing at least one of said hexagonally shaped flexible members through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through the septum primum. Claim 37 also recites that the at least one hexagonally shaped flexible member is withdrawn from the left atrial side.

As previously discussed, Roe teaches a device for delivering a closure element, such as a staple, for closing vascular puncture sites, for example, in blood vessels (col. 1, lines 16-18; col. 3, lines 26-31). Roe does not teach using his device in the heart, let alone, to close patent foramen ovales. Accordingly, Roe does not teach introducing at least one hexagonally shaped flexible members through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through the septum primum, nor does Roe teach that the at least one hexagonally shaped flexible members is withdrawn from the left atrial side.

While Das teaches that a hexagonally shaped septal occluder can be introduced to occlude a septal defect (col. 10, lines 5-9; FIG. 5C; and FIG. 10), Das does not teach removing the hexagonally shaped occlusion device from the patent foramen ovale. In contrast to Das, Applicants' claimed invention requires that the at least one hexagonally shaped flexible member is withdrawn from the left atrial side of the patent foramen ovale.

The Examiner has provided no reason to modify Roe in view of Das to introduce at least one hexagonally shaped flexible member through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left

atrial side prior to introducing a hole through the septum primum and to withdrawn the at least one hexagonally shaped flexible member from the left atrial side.

Further, none of the remaining references cited by the Examiner, *e.g.*, Ginn or Sawyer teach introducing at least one hexagonally shaped flexible members through the opening of a patent foramen ovale by entering the opening of the patent foramen ovale from the right atrial side, passing through the tunnel of the patent foramen ovale and exiting the opening of the patent foramen ovale on the left atrial side prior to introducing a hole through the septum primum.

Rather, Ginn teaches only that a puncture devices travels from one atrial side of the heart to the other by puncturing through the septum. Sawyer does not even teach patent foramen ovales.

For all these reasons, Applicants respectfully submit that claim 37 is patentable in view of the references cited. Applicants further submit that claim 40, depending from claim 37, is patentable for the same reasons that claim 37 is patentable. Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Claims 38 and 39 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Roe in view of Das and Ginn. Claims 38 and 39 have been canceled. Accordingly, Applicants respectfully request that the rejection of claims 38 and 39 be reconsidered and withdrawn.

CONCLUSION

Applicants submit that the pending claims are in condition for allowance. Applicants respectfully request that the Examiner telephone the undersigned attorney to discuss any outstanding issues.

Respectfully submitted,

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